

Determining Efficacy of the Combined Application of Electrical Stimulated Antagonist  
Contraction During Walking with Sensory TENS for Increasing Strength and Decreasing Pain in  
Women with Frequent Knee Symptoms

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**RESEARCH CONSENT FORM**  
**Determining Efficacy of the Combined Application of Electrical Stimulated Antagonist Contraction During Walking with Sensory TENS for Increasing Strength and Decreasing Pain in Women with Frequent Knee Symptoms**

Protocol: HTS  
Investigator: Neil Segal, MD  
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913-588-6777

You are being asked to join a research study. Participating in research is different from getting standard medical care. The main purpose of research is to create new knowledge for the benefit of future patients and society in general. Research studies may or may not benefit the people who participate.

Research is voluntary, and you may change your mind at any time. There will be no penalty to you if you decide not to participate, or if you start the study and decide to stop early. Either way, you can still get medical care and services at the University of Kansas Medical Center (KUMC).

This consent form explains what you have to do if you are in the study. It also describes the possible risks and benefits. Please read it carefully and ask as many questions as you need to, before deciding about this research.

You can ask questions now or anytime during the study. The researchers will tell you if they receive any new information that might cause you to change your mind about participating. You may be asked to sign a new consent form if this occurs.

This research study will take place at the University of Kansas Medical Center (KUMC) with Neil Segal, MD as the researcher. About 28 women will be in the study at KUMC.

**Why am I being asked to take part in this study?**

You are being asked to take part in this study because you have frequent knee symptoms.

**Why is this study being done?**

Osteoarthritis of the knee (KOA) is the most common cause of disability in older adults.

Osteoarthritis involves a loss of cartilage, which acts like a cushion between your bones as well as changes in the bones of joints. Once the joint cartilage is gone, the body does not produce new cartilage. Joint damage can contribute to pain.

Currently, treatment for pain associated with knee osteoarthritis includes exercise. However, exercise at a medium- to high-intensity level can be a problem for people with knee pain. Because exercise is a common treatment for knee pain but many people experience pain during exercise, researchers hope to find a safer and more effective exercise method to strengthen the muscles around the knee.



Both aerobic exercise and resistance exercise are recommended for the treatment of people with knee pain. However, pain can be a barrier to participating in exercise at a moderate or vigorous intensity. Electrical stimulation of muscles holds potential to allow effective exercise to be completed at tolerable intensities.

Transcutaneous electrical nerve stimulation (TENS) is the use of very low electric currents produced by a device to stimulate the nerves, to treat pain. Neuromuscular electrical stimulation (NMES) uses low electrical current to cause muscles to contract.

By doing this study, we hope to learn if a hybrid training system (HTS), using a combination of NMES and walking, is effective in strengthening muscles in people with knee pain, aching or stiffness.

### **What is being tested in this study?**

This study will assess whether electrical stimulation of muscles during walking twice each week for 3 months improves strength and relieves pain.

### **How long will I be in the study?**

Your participation in this study is expected to last about 12 weeks (2 times per week separated by at least 48 hours), and will include up to 26 study visits.

### **What will I be asked to do?**

If you decide to join the study, you will be asked to read and sign this consent form before any study procedures take place.

If you are eligible to be in this study, you will be assigned, using a random number generator (like flipping a coin), to one of these two groups (50% chance):

- Electrical stimulation with Hybrid Training System
- Electrical stimulation with TENS

You will be asked to participate in walking exercises while wearing one of the two devices used in this study (TENS unit or NMES unit). Tests will also be performed of your mobility, strength, and pain perception.

The first and last visits (Baseline and Visit 25) will occur at the Clinical and Translational Science Unit (CTSU) located at 4350 Shawnee Mission Parkway, Fairway, KS, 66205

The exercise visits (Visits 1-24) will occur at the Kirmayer Fitness center located at the University of Kansas Medical Center, 3901 Rainbow Blvd., 1001 Kirmayer Fitness Center, Kansas City, KS, 66160. The Kirmayer Fitness Center is located on the southwest corner of the medical center campus on Olathe Blvd.

Below, you will find a schedule of events listing all procedures that will occur at each



study visit. Following the table, you will find a description of the study procedures.

	Baseline	Intervention Period		
Assessment		Visits 1, 2, 3, 12, 24	Visits 4-11, 13-23	Visit 25
Informed Consent	X			
Vital signs	X			
Questionnaire	X			X
Questions about your pain	X	X	X	X
Test for threshold value of pain	X	X		X
Movement assessment	X			X
Strength Testing	X			X
Walking exercise with Electrical Stimulation		X	X	
Discuss side effects		X	X	X
Estimated Length of Visit (in hours)	2.5	0.75	0.5	1

**The following is a description of each procedure listed in the previous table:**

Informed Consent: At the first study visit, the study will be explained to you. If you decide to participate in this study, you will be asked to read and sign this consent form before any tests or procedures can be completed. You will be given a copy of the signed informed consent.

Vital Signs: Your vital signs (blood pressure, heart rate, and breathing rate) will be taken.

Questionnaire: You will be asked to complete a questionnaire about how your knee symptoms are affecting your daily activities.

Urine sample: If there is a possibility that you could be pregnant, you will be asked to complete a urine pregnancy test before study participation. If you are pregnant, you cannot be in this study.

Questions about your pain: You will be asked questions about how much knee pain you are experiencing. Your pain will be measured on a visual pain scale (a chart representing your pain with numbers, with 0 being no pain at all and 10 being the worst pain imaginable).

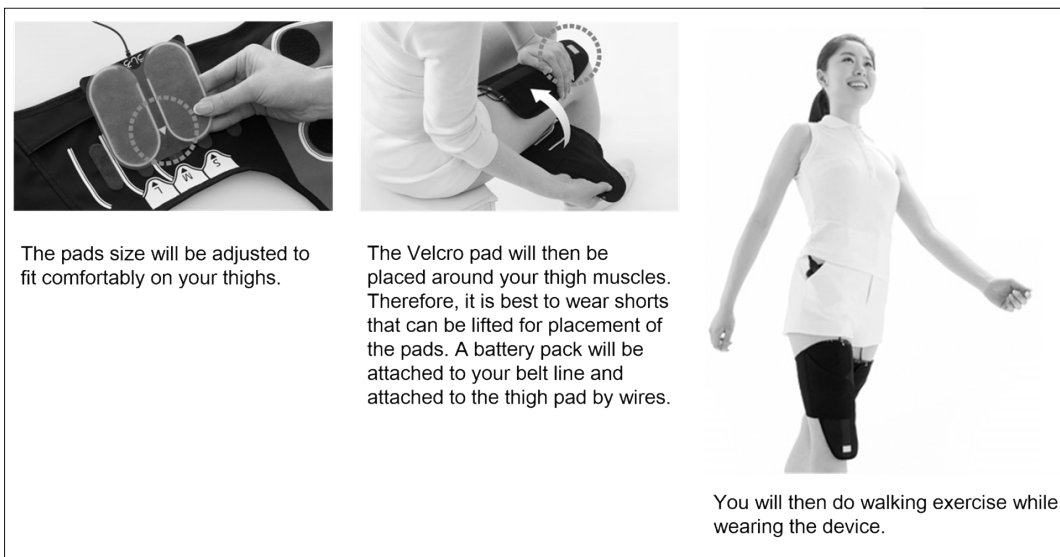
Test for threshold value of pain: Your pressure pain threshold will be measured using a hand-held pressure algometer. This is an instrument that presses on your skin and records the level when you report discomfort.



Movement Assessment: You will be asked perform basic physical activities such as standing up from a chair, walking in a straight line and climbing stairs. You will be timed during each activity.

Strength Testing: Your strength in each leg will be tested before and after the 3 months of walking exercise training (explained below).

Walking Exercise with Electrical Stimulation: You will be asked to perform walking exercise while low-energy electrical stimulation is being applied to your thigh. Electrical sensors will be placed on your upper legs before the training exercise begins. These sensors will deliver low-energy electrical pulses to your legs. You might experience a small amount of discomfort in your muscles after exercising with electrical stimulation. The study team member will lead you through a warm-up, the exercise and a cool-down over a 30-minute period. These walking exercises will be performed at the Kirmayer Fitness Center at the University of Kansas Medical Center. You will be instructed to avoid excessive exercise outside of the study to avoid over-fatigue during the study period.



Discuss side effects: You will be asked questions about how you are feeling and any side effects you may have experienced.

### **What are the possible risks or discomforts?**

The study intervention may cause side effects or other problems. The researchers will be checking your medical information during the study to watch for side effects. However, you should tell the research team about anything that is bothering you or any changes in your health since the last visit. The researchers may be able to take steps to reduce side effects. You may experience none, some, or all of the side effects listed below. There may be other side effects or risks that are not yet known.



### Strength Testing and Exercise Risks

You may experience sore muscles. This soreness is expected to be minimal and will go away in a short period of time. This risk will be minimized by the trained study staff member observing you and offering guidance throughout your exercise and strength testing sessions.

As with any physical activity, there is a risk of experiencing high/low blood pressure, fainting, irregular heartbeat, or heart attack.

### Electrical Stimulation Risks

You may experience a small amount of discomfort in your muscles when they are being treated with electrical stimulation. This discomfort will go away once the electrical stimulation ends. If you are unable to continue to exercise because of this discomfort you can stop and the study team will lower the amount of electrical stimulation until the discomfort goes away. If the discomfort continues you will be withdrawn from the study. The adhesive patches on your legs used for the electrical stimulation may cause redness, rash, or itching like a heat rash. This risk will be minimized by a trained study staff member observing you, only wearing the patch during the walking sessions and using a new patch every 2 weeks. If you have repeated skin reactions to the adhesive patches and are unable to continue the study exercise you will be withdrawn from the study.

### **Are there benefits to being in this study?**

You may or may not benefit from this study. If the study intervention is effective, you may develop greater muscle strength and/or experience less knee pain. Researchers hope that the information from this research study may be useful in the treatment of other patients with knee symptoms.

### **Will it cost anything to be in the study?**

The study will pay for all study-related medical services provided during this study. These services include the intervention, study visits, and study related tests and procedures such as the physical exams, exercise training, urine pregnancy test if needed, and all questionnaires as listed in this consent form.

Any other medical visits and procedures you have outside of the study due to other standard of care treatments or other health issues are billable to you or your insurance through normal hospital billing practices. Standard of care means necessary for the care of a medical issue as determined by your doctor and not necessary for this study.

Your insurance may not cover some or all of the standard care services if you are part of a research study. You may want to talk to your insurance company and review your specific benefits and coverage before deciding to participate. You will be responsible for normal co-pays, deductibles and non-covered services that are not the responsibility of the study. Some procedures require Pre-Certification from your insurance company,



and representatives of the clinic or hospital will be helping you with that process. Pre-Certification is not a guarantee of payment.

You can still be in the study even if your insurance denies coverage for your standard of care treatment or if you are uninsured. The hospital has a financial assistance program which it makes available to all patients who qualify. If your insurance denies coverage and you do not qualify for the financial assistance, you will be charged for all bills that are not the responsibility of the study. The study staff will be able to provide more information to you.

**Will I get paid to participate in the study?**

You will receive \$25 for the first study visit and \$75 after completing the final study visit. If you are unable to complete all visits then the \$75 will be divided by the number of visits you did participate in. If you complete all regularly scheduled visits, you may receive up to \$100. If your participation ends early, you will be paid only for the visits you completed.

You will be given a ClinCard, which works like a debit card. After a study visit, payment will be added onto your card by computer. The money will be available within 1 business day. You can use the ClinCard at an ATM or at a store. No one at KUMC will know where you spent the money. You will be given one card during the study. If your card is lost or stolen, please call (866) 952-3795.

The KUMC Research Institute will be given your name, address, social security number, and the title of this study to allow them to set you up in the ClinCard system. Study payments are taxable income. A Form 1099 will be sent to you and the Internal Revenue Service if your payments are \$600 or more in a calendar year.

Your personal information will be kept on a secure computer. It will be removed from the computer after the study is over and the money on the card has been used. Your information will not be shared with other businesses. It will be kept completely confidential.

**Will the researchers get paid for doing the study?**

This study is being funded by Kurume University in Japan. These funds will be used for research purposes only.

**What happens if I get hurt or sick during the study?**

If you have a serious side effect or other problem during this study, you should immediately contact Dr. Segal at 913-588-6777. If it is after 5:00 p.m., a holiday or a weekend, you should call 913-588-5000 and ask for the operator to contact Dr. Segal. A member of the research team will decide what type of treatment, if any, is best for you at that time.

If you have a bodily injury as a result of participating in this study, treatment will be provided for you at the usual charge. Treatment may include first aid, emergency care





and follow-up care, as needed. Claims will be submitted to your health insurance policy, your government program, or other third party, but you will be billed for the costs that are not covered by the insurance. You do not give up any legal rights by signing this form.

If you think you have been harmed as a result of participating in research at the University of Kansas Medical Center (KUMC) or one of its affiliates, you should contact the Director, Human Research Protection Program at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160. You may also telephone (913) 588-1240.

**Do I have to be in the study?**

Being in research is voluntary. You can choose whether or not to participate. Even if you decide not to join the study, you can still come to KUMC for services and treatment.

**What other choices do I have?**

You can choose not to be in the study. Instead of being in this study, you can receive treatment that is already available, such as exercise to strengthen muscles important to knee joint function, injections, pain medications for osteoarthritis pain, and surgical procedures. You may wish to discuss alternatives with the study doctor.

**How will my privacy be protected?**

The researchers will protect your information, as required by law. Absolute confidentiality cannot be guaranteed because persons outside the study team may need to look at your study records. Your health information is protected by a federal privacy law called HIPAA. By signing this consent form, you are giving permission for KUMC to use and share your health information. If you decide not to sign the form, you cannot be in the study.

The researchers will only use and share information that is needed for the study. To do the study, they will collect health information from the study activities and from your medical record. Your medical records at KUMC may contain information such as name, address, phone, date of birth, social security number, or other identifiers. Your health information will be used at KUMC by Dr. Neil Segal, members of the research team, The University of Kansas Hospital Medical Record Department, the KUMC Research Institute and officials at KUMC who oversee research, including members of the KUMC Human Subjects Committee and other committees and offices that review and monitor research studies.

By signing this form, you are giving Dr. Segal and the research team permission to share information about you with persons or groups outside KUMC. Your information will be shared with representatives of Kurume University (the sponsor of the study), other business partners of the sponsor who help with the study and the study's co-investigator, Hiroo Matsuse, MD. They may make copies of study records for audit purposes. The purpose for using and sharing your information is to make sure the study is done properly and to evaluate the safety and effectiveness of the study.





intervention.

The HIPAA privacy law may not apply to everyone who receives your health information. Your information might not be protected by HIPAA if persons outside KUMC disclose it. In some cases, there may be other laws that protect your information from improper use.

Your permission to use and share your health information will not expire unless you cancel it. Any research information that is placed in your medical record will be kept indefinitely.

While you are participating in this study, you may see and copy any study information that is placed in your KUMC medical record. However, some study information is kept only by the researcher. The records kept only by the researcher may not be available to you until the end of the study.

The researchers may publish the results of the study. If they do, they will only discuss group results. Your name will not be used in any publication or presentation about the study.

### **Can I stop being in the study?**

You may stop being in the study at any time. Your decision to stop will not prevent you from getting treatment or services at KUMC.

You have the right to cancel your permission for researchers to use your health information. If you want to cancel your permission, please write to Dr. Segal. The mailing address is Neil Segal, MD, University of Kansas Medical Center, 3901 Rainbow Boulevard, Kansas City, KS 66160. If you cancel permission to use your health information, you will be withdrawn from the study. The researchers will stop collecting any additional information about you unless they need information about a side effect of the study intervention. They may use and share information that was gathered before they received your cancellation.

### **Could my participation be stopped early?**

This study might be stopped, without your consent, by the investigator, the sponsor or by the FDA. Your participation also might be stopped by the investigator or by the sponsor if it is in your best interest or if you do not follow the study requirements.

Neither the sponsor, nor the investigator, nor the University of Kansas Medical Center will be obligated to provide you with the study intervention or treatment if the study is stopped early. Your physician will decide about future treatment, if it is needed.

### **Who can I talk to about the study?**

Before you sign this form, Neil Segal, MD, or other members of the study team should answer all your questions. You can talk to the researchers if you have any more



questions, suggestions, concerns or complaints after signing this form. If you have any questions about your rights as a research subject, or if you want to talk with someone who is not involved in the study, you may call the Human Subjects Committee at (913) 588-1240. You may also write the Human Subjects Committee at Mail Stop #1032, University of Kansas Medical Center, 3901 Rainbow Blvd., Kansas City, KS 66160.



### CONSENT

Dr. Segal or the research team has given you information about this research study. They have explained what will be done and how long it will take. They explained any inconvenience, discomfort or risks that may be experienced during this study.

By signing this form, you say that you freely and voluntarily consent to participate in this research study. You have read the information and had your questions answered.

***You will be given a signed copy of the consent form to keep for your records.***

\_\_\_\_\_  
Print Participant's Name

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Time

\_\_\_\_\_  
Date

\_\_\_\_\_  
Print Name of Person Obtaining Consent

\_\_\_\_\_  
Signature of Person Obtaining Consent

\_\_\_\_\_  
Date

